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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,279	09/27/2005	Ken Tatebe	1029650-000173	1584
21839	7590	06/10/2010	EXAMINER	
BUCHANAN, INGERSOLL & ROONEY PC			KWAK, DEAN P	
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ALEXANDRIA, VA 22313-1404			ART UNIT	PAPER NUMBER
			1797	
			NOTIFICATION DATE	DELIVERY MODE
			06/10/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com
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Office Action Summary	Application No.	Applicant(s)	
	10/551,279	TATEBE ET AL.	
	Examiner	Art Unit	
	Dean Kwak	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10 December 2009.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1 and 4-7 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1 and 4-7 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Status

1. The finality of the previous Office Action dated 9/10/09 has been withdrawn.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1 & 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tatebe et al. (Japanese Patent Application No. Hei 11-352306, JP 2001-165930; see English translated version).

Regarding Claims 1 & 6, Tatebe et al. disclose a test paper (e.g., test strip, Abstract & P10/[0008]/L4) comprising a porous membrane (Abstract & P10/[0008]/L13 & 17) having a function of separating an object that should be filtered out from a sample by filtration and carrying thereon a reagent (P3/Claim 1) capable of giving a color by reaction with a specified component in the sample (P5/Claim 8 & P16/[0018]/L1),

- wherein said porous membrane has a first layer having a surface to which a sample is supplied (Abstract & P10/[0008]/L12-15) and a second layer having a surface at which the sample is percolated and measured (Abstract & P10/[0008]/L16-P11/[0008]/L1),
- said first layer being made of large-sized pore portions (P10/[0008]/L13-15), with a surface of said first layer being a smooth surface having apertures thereat (e.g., porous, P10/[0008]/L13), said second layer being made of small-sized pore portions (P10/[0008]/L17-18), with a surface of said second layer having apertures thereat (e.g., porous, P10/[0008]/L17),
- wherein said first layer and said second layer are integral with each other and are not separate layers stacked together (see P20/L4-5, “the first and second layers

may be bonded together with an adhesive or may be fusion-bonded with each other”), and

- wherein said porous membrane has a thickness of 50 to 200 μm (P3/Claim 2, P4/Claim 3, P11/[0009]/L4 & 12) and a porosity of 60 to 95% (P3/Claim 2, P4/Claim 3, P11/[0009]/L5 & 13), said first layer has an average pore size of 0.5 to 10 μm (P3/Claim 2 & P11/[0009]/L3, 3 to 10 μm) in the surface thereof, and said first layer is located from the surface of said first layer within a range of 1/5 to 1/2 of a thickness of said porous membrane (see P11/[0009]), and said second layer has an average pore size of 0.1 to 3.0 μm (P4/Claim 3 & P11/[0009]/L11-12, 0.1 to 2 μm) in the surface thereof.

Regarding Claims 1 & 6, Tatebe et al. disclose all of the claim limitations as set forth above. While Tatebe et al. do not explicitly disclose the second layer surface having glossiness of not higher than 11 according to JIS Z8741, the change in the surface glossiness is not considered to confer patentability to the claims. Tatebe et al. utilize optical measurement (e.g., spectrophotometer, P25/[0038]/L5) and light reflection absorbance at the surface of the membrane (P25/[0038]/L7-P26/[0038]/L1) are measured, where the results are determined by change in refection. Therefore the surface glossiness or the surface reflectivity is a variable that can be modified, among others, by varying the surface of the material used. For that reason, the surface, and membrane material, would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the surface glossiness cannot be considered critical. Accordingly, one of

ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the membrane in the apparatus of Tatebe et al. to obtain the desired surface glossiness according to JIS Z8741 not higher than 11 (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

In addition, in regards to the section density limitations, it is noted that Tatebe et al. disclose properties of the membrane (i.e., thickness, porosity, pore size) in which are related to the density of the membrane. As such, said limitations have been implicitly disclosed. In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to alter the membrane property (i.e., density) to modify, such as, filtering components and flow rates, to meet the experimental needs. It is noted that as the density, porosity, pore size, thickness are variables that can be modified, among others, by adjusting said density of the membrane the precise coating thickness would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed density cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the density of the membrane of to obtain the desired operation efficiency (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

Further, in regards to the first layer and the second layer together constitute a single membrane portion formed by a single casting operation, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the layers integrally to ease handling of the device. It is noted that the use of a one piece construction instead of the structure disclosed in prior art would be merely a matter of obvious engineering choice., see *In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965) & MPEP 2144. In addition, regarding limitations recited above, which are directed to method of making the single membrane (e.g., “*formed by a single casting operation*”), it is noted that said limitations are given little patentable weight in the product claims. Even though a product-by-process is defined by the process steps by which the product is made, determination of patentability is based on the product itself and does not depend on its method of production. *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). As the court stated in *Thorpe*, 777 F.2d at 697, 227 USPQ at 966 (The patentability of a product does not depend on its method of production. *In re Pilkington*, 411 F.2d 1345, 1348, 162 USPQ 145, 147 (CCPA 1969). If the product in a product-by-process claim is the same or obvious as the product of the prior art, the claim is unpatentable even though the prior art product was made by a different process.). See MPEP 2113 and 2114. Therefore, since the membrane as recited in claims 1 and 6 is the same as the membrane disclosed by Tatebe et al., as set forth above, the claim is unpatentable even though it was made by a different process. *In re Marosi*, 710 F2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983).

Regarding Claims 4, 5 & 7, Tatebe et al. disclose all of the claim limitations as set forth above. In addition, Tatebe et al. disclose the test paper wherein:

- a material for said porous membrane is made of polyether sulfone (P11/[0010]/L4),
- said sample is a blood and said object that should be filtered out contains blood cells (P12/[0010]/L1-3), and
- a ratio between the average pore size in the surface of said first layer and the average size in the surface of said second layer is in the range of 1 to 6 (P11/[0009]/L5-17).

Response to Arguments

6. Applicant's arguments filed 12/10/2009 have been fully considered but they are not persuasive.

In response to applicant's arguments regarding the membranes manufactured as a single membrane by a single casting operation, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the layers integrally to ease handling of the device. It is noted that the use of a one piece construction instead of the structure disclosed in prior art would be merely a matter of obvious engineering choice., see *In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965) & MPEP 2144.

In addition, regarding limitations recited above, which are directed to method of making the single membrane (e.g., “*formed by a single casting operation*”), it is noted that said limitations are given little patentable weight in the product claims. Even though a product-by-process is defined by the process steps by which the product is made, determination of patentability is based on the product itself and does not depend on its method of production. *In*

re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). As the court stated in *Thorpe*, 777 F.2d at 697, 227 USPQ at 966 (The patentability of a product does not depend on its method of production. *In re Pilkington*, 411 F.2d 1345, 1348, 162 USPQ 145, 147 (CCPA 1969). If the product in a product-by-process claim is the same or obvious as the product of the prior art, the claim is unpatentable even though the prior art product was made by a different process.). See MPEP 2113 and 2114. Therefore, since the membrane as recited in claims 1 and 6 is the same as the membrane disclosed by Tatebe et al., as set forth above, the claim is unpatentable even though it was made by a different process. *In re Marosi*, 710 F2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983).

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1797

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dean Kwak whose telephone number is 571-270-7072. The examiner can normally be reached on M-TH, 5:30 am - 4:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

25May10

/D. K./
Examiner, Art Unit 1797

/LYLE A ALEXANDER/
Primary Examiner, Art Unit 1797